

VARIABLE REFRACTIVE POWER, EXPANDABLE INTRAOCULAR LENSES

FIELD OF THE INVENTION

Intraocular lenses for implanting inside aphakic eyes are the general province of this invention. This invention specifically relates to intraocular lenses whose central lenticular means initially is collapsed or unexpanded during insertion and implantation in the eye. This design obviates the need for a relatively large incision (greater than 4 mm) in the eye. The lens can be inserted through a relatively small incision (4 mm or less) in the eye.

The intraocular lenses of this invention can be implanted either in the posterior chamber or in the capsular bag. After placement in the eye, the bag means or chambers of the central lenticular means can be expanded by filling with the proper amount of a physiologically compatible fluid calculated to result in the correct refractive power for the patient. Moreover, after implantation if it becomes necessary to remove the lenses or to change their refractive power, only a small surgical incision is necessary.

For complete removal of the implanted lens, a syringe and needle can be used to extract the fluid and collapse the bag means by either puncturing the bag means or by accessing the tube means initially used to fill the bag means or chambers. Removal then can be accomplished through a similarly, relatively small (4 mm or less) incision. If only the refractive power of the implanted lenses need be changed, a syringe and needle can be used to add or remove physiologically compatible fluid by accessing through the tube means.

BACKGROUND OF THE INVENTION

Currently cataract extraction is the most common ophthalmic surgical procedure performed in the United States. Roughly, over 450,000 lenses are removed every year. These natural lenses, however, must be replaced with a prosthetic optical device before useful vision can be restored to the operated eye. Light rays no longer are focused on the retina with the lens removed. Vision is very poor without corrective glasses, contact lenses or an intraocular lens.

Corrective eye glasses have been the classic and most common method of correcting aphakia. Corrective glasses, however, being located in front of the normal position of the human lens, can produce magnification which distorts the shape of viewed objects. Contact lenses cause less magnification and distortion, but very old and very young patients frequently find handling and wearing these small lenses difficult. With implanted intraocular lenses, there is little or no magnification or distortion. Also, there is no need to remove the intraocular lens from the eye or otherwise handle the lens. Generally, intraocular lenses provide good visual acuity at all times, even at night.

Intraocular lenses have definite advantages in terms of vision and convenience over the other methods of aphakic correction. While intraocular lenses have definite advantages over corrective glasses and contact lenses, intraocular lenses have specific disadvantages.

Intraocular lens implantation surgery is more traumatic than simple cataract extraction alone. The additional handling of the cornea and manipulation inside the anterior chamber during lens implantation add to the amount of trauma to the eye. Extreme care must be

exercised to limit trauma to the cornea, structures of the anterior chamber, and other structures.

Generally, during implant surgery, a 7-8 mm incision is made in the conjunctiva just outside the cornea so that the patient's lens can be removed and replaced with an implant intraocular lens. Incision length is dictated more by the size of the intraocular lens to be implanted than by the requirement of removing the patient's natural lens. For example, the patient's natural lens can be removed using an ultrasonic instrument which requires an incision much smaller than is needed to insert intraocular lens implants currently available.

The ability to change refractive power of an implanted intraocular lens without an additional surgical implant operation is a desired benefit. It is particularly desirable in very young patients. Size and shape of the eyeball in very young patients change as they mature. The distance from the lens to the retina changes as the size of the eye changes. A lens of the correct refractive power when implanted may not later correctly focus light entering the eye and passing to the retina. Changes in the refractive power of lenses in very young patients may be indicated after as little time as one year. It is the antithesis of limiting trauma associated with lens implants when a surgical procedure is dictated within such a short period of time.

A large number of different types and styles of intraocular lenses has been developed. Major classes of lenses can be distinguished based on the method of fixation in the eye. Anterior chamber lenses lie entirely in front of the iris. Iris-supported lenses rely on the structural integrity of the iris to stabilize and support the lens within the eye. Capsule-fixated lenses are inserted into a planned extracapsular cataract extraction space between the iris and posterior leaves of the lens capsule. Common to most lenses in use today are their reliance on haptics, also called feet or loops, emanating from the lenses and intended to support and fix the lens in the eye.

Trauma to the eye associated with lens implants is related to incision length. Efforts to minimize overall intraocular lens size, and hence reduce trauma, have so far concentrated on collapsing or folding haptic loops prior to insertion. Substantive efforts in this regard, along with attempts of others, may be found in U.S. patent applications Ser. Nos. 490,858, *Intraocular Lenses with Openable Haptic Loops*, filed May 2, 1983, and 800,728, *Intraocular Lenses with Latchable Haptic Loops*, filed Nov. 22, 1985 both to Peyman, commonly owned with this application by Gholam A. Peyman, M.D.

That the lenses always have to be larger than the incision provided for their implant in the eye is a principal cause of trauma. Implantation of currently used lenses in their proper position within the eye often requires the reduction of lens size inside the eye during surgery. In this microfine surgery uncommon agility on the part of even a skilled surgeon often is required. Space limitations in the eye, the required size of the lens once implanted, and considerable manipulations of the lenses during implantation by the surgeon can result in traumatic damage to the corneal endothelium and very often rupture of the posterior capsule by the novice. Damage to the corneal endothelium and rupture of the posterior capsule are complications considered serious.

Some attempts have been made to reduce the size of the central lenticular portion of intraocular lenses prior to insertion. Silicon lenses which can be folded and gel-type lenses which absorb intraocular fluid and sub-